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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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09/151,885 09/11/98 COSTIN

J 98-WL-1

EXAMINER

004370 HM22/0131  
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| WHITE, F |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |

1623  
DATE MAILED:

9  
01/31/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/151,885**

Applicant(s)

**COSTIN**

Examiner  
**Everett White**

Group Art Unit  
**1623**



☒ Responsive to communication(s) filed on Nov 8, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 5 and 6 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 5 and 6 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. The request filed on November 8, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/151,885 is acceptable and a CPA has been established. An action on the CPA follows.
2. Amendment B' filed November 8, 2000 has been received and entered into the record.
3. Claims 5 and 6 are pending in the case. Claim 1-4 have been canceled.
4. All 35 U.S.C. statutes not cited in this Office action can be found cited in full in a previous Office action.

#### **Disclosure Objected To**

5. The disclosure is objected to because of the following informalities: On page 2, lines 8 and 9 of the instant specification, the specification disclose the statement that "4,4'-methylene bis(tetrahydro-1,2,4 thiadiazine-1,2-dioxide) is known generically as Taurolidine". However, there is evidence that this nomenclature for Taurolidine is incorrect. See the sheet attached to the end of this Office Action which suggests that the nomenclature for Taurolidine is 4,4'-methylene bis (perhydro-1,2,4 thiadiazine-1,1-dioxide)).

The compound "4,4'-methylene bis(tetrahydro-1,2,4 thiadiazine-1,2-dioxide" having the 1,2-dioxide group does not appear to be a stable compound. Applicants are requested to provide the structure for the compound 4,4'-methylene bis (tetrahydro-1,2,4 thiadiazine-1,2-dioxide so that the Examiner will have a better understanding of the claimed invention.

Appropriate correction is required.

#### **35 U.S.C. 112, First Paragraph Rejection**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly added Claims 5 and 6 which are directed to a method for reducing the ability of microorganisms to adhere to epithelia cells is not supported in the instant specification. Not only is the claimed invention not disclosed in the instant specification, but the term "epithelia cells" appears not to have been mentioned in the specification. Hence, Claims 5 and 6 set forth new matter which is improper under 35 U.S.C. 112, first paragraph.

8. Applicant's arguments with respect to claims 5 and 6 have been considered but are moot in view of the new ground(s) of rejection.

### **35 U.S.C. 103 Rejection**

9. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blenkarn (Surgical Res. Commun., Vol. 2, pp 149-155 (1987), already of record).

Applicant claims a method for reducing the ability of microorganisms to adhere to epithelial cells which comprises contacting the epithelial cells with a sterile solution containing from about 0.05% to about 2.0% w/v of 4,4'-methylene bis(tetrahydro-1,2,4 thiadiazine-1,2-dioxide) for a period of time of up to thirty minutes. Applicant also claims that the method may comprises contacting the microorganism with the sterile solution of 4,4'-methylene bis(tetrahydro-1,2,4 thiadiazine-1,2-dioxide).

The Blenkarn reference discloses a closely related compound to 4,4'-methylene bis(tetrahydro-1,2,4 thiadiazine-1,2-dioxide), Taurolidine, as having anti-adhesive properties with regard to the prevention of peritoneal adhesions and the adhesion of microorganism to epithelial surfaces as set forth for the 4,4'-methylene bis(tetrahydro-1,2,4 thiadiazine-1,2-dioxide) in the instant claims. These compounds only differ by setting forth a 1,1-dioxide group for Taurolidine as opposed to a 1,2 dioxide group for the compound used in the instantly claimed invention. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant(s) invention to replace the Taurolidine compound of the Blenkarn reference with the

4,4'-methylene bis(tetrahydro-1,2,4 thiadiazine-1,2-dioxide) compound in view of their closely related structures and the resulting expectation of similar anti-adhesive properties.

10. Applicant's arguments with respect to claims 5 and 6 have been considered but are moot in view of the new ground(s) of rejection.

11. **Summary:** All the pending claims (Claims 5 and 6) are rejected.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 8:30 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*E. White*

White

January 26, 2001



GARY GEIST  
SUPERVISORY PATENT EXAMINER  
TECH CENTER 1600